

Message Text

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ACTION EA-09

INFO OCT-01 ISO-00 AID-05 CEQ-01 CIAE-00 OFA-01 COME-00

DODE-00 EB-07 EPA-01 INR-07 IO-11 L-03 NSF-01 NSC-05

NSAE-00 PM-04 USIA-06 OES-03 SS-15 SP-02 INT-05 FEA-01

AGR-05 STR-04 PA-01 PRS-01 /099 W

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R 300900Z JAN 76

FM AMEMBASSY TOKYO

TO SECSTATE WASHDC 6525

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E.O. 11652: N/A

TAGS: ETRD EAGR KA

SUBJECT: CITRUS WAXES AND FUNGICIDES

DEPARTMENT PASS AGRICULTURE FOR FITZSIMMONS

REF: (A) TOKYO 0761 (B) TOKYO 0840 (C) TOKYO AIRCOMM

NO. 36 (3-17-75) (D) FASTO 72 (E) TOFAS 37

1. SUMMARY: AGATT AND ASST HAVE VISITED KEY OFFICIALS IN MAF, MHW AND INSTITUTE OF ENVIRONMENTAL TOXICOLOGY (IET) OVER PAST FIVE DAYS. AS RESULT HAVE LEARNED THAT IET PLANNING BEGIN MUTAGENICITY RESEARCH ON OPP AND TBZ ASAP, FUNDED BY PRIVATE SOURCES. EVERY EFFORT BEING MADE KEEP ISSUE OUT OF PRESS. SOME CONCERN THAT NECESSARY RESEARCH WILL NOT BE COMPLETED IN TIME TO AVOID HIGH SUMMER PRICES FOR LEMONS DUE TO SPOILAGE. PERHAPS SOME SLIGHT POSSIBILITY THAT FOOD SANITATION INVESTIGATION COUNCIL (FSIC) COULD MEET BEFORE COMPLETION OF RESEARCH TO CONSIDER PROVISIONAL APPROVAL IN EFFORT TO AVOID COMPLICATIONS OF SPOILAGE. MHW INSPECTION PROCESS FOR WAXES WILL BE SAME AS IN PAST EXCEPT NON-NATURAL SUBSTANCES MUST BE LISTED EFFECTIVE MARCH 1. END SUMMARY.

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2. AGATT MET WITH MAF DIR GEN SAWABE JAN 26 TO THANK

HIM FOR COOPERATION DURING ASST SEC BELL'S VISIT AND INQUIRE
RE PROGRESS ON SEVERAL ISSUES INCLUDING OPP/TBZ.

3. SWABE, WHO HAD JUST BEEN BRIEFED BY DR SHIRASU (RECENTLY
RETURNED FROM U.S.), STATED THAT MUTAGENICITY RESEARCH WILL
PROBABLY BEGIN SOMETIME IN FEB AND MAY TAKE FOUR OR FIVE
MONTHS TO COMPLETE. HE ALSO POINTED OUT THAT DR SHIRASU HAD
LEARNED THAT EPA WILL, WITHIN ONE YEAR, REQUIRE MUTAGENICITY
DATA ON ALL NEW PESTICIDES FOR WHICH REGISTRATION IS REQUESTED
AND THAT PROBABLY REPEAT PROBABLY WITHIN SIX YEARS EPA WILL
REQUIRE SUCH DATA ON ALL PREVIOUSLY REGISTERED CHEMICALS,
INCLUDING OPP AND TBZ. SAWABE SAID, USDA ASKED DR SHIRASU
IF MHW COULDN'T GIVE PROVISIONAL APPROVAL OF CHEMICALS BEFORE
MUTAGENICITY RESEARCH COMPLETED. THIS, HE EXPLAINED, IS MHW
PROBLEM BUT UNDER CURRENT LAW PROVISIONAL APPROVAL MAY BE
IMPOSSIBLE.

4. MHW FOOD CHEMISTRY SECTION CONTACTED AGATT OFFICE JAN 27
AND REQUESTED (A) TERATOGENICITY DATA ON OPP (NONE EXISTS IN
DATA PACKAGE SUBMITTED TO DATE). , (B) ANY ADDITIONAL LONG TERM
TOXICOLOGICAL DATA AVAILABLE ON OPP,
(ONLY ONE REPORT ON THIS FOUND IN U.S. DATA PACKAGE), (C)
ANY ADDITIONAL TERATOGENICITY AND/OR LONG TERM TOXICOLOGY
DATA ON TBZ. AGATT TEP EXPLAINED THAT MANY TIMES IN PAST (AS
MUCH AS SIX MONTHS AGO) THE FACT THAT TERATOGENICITY DATA FOR
OPP WAS NOT INCLUDED IN DATA PACKAGE SUBMITTED BY U.S. HAD
BEEN DISCUSSED AND MHW/CHEM GAVE AGATT IMPRESSION DATA'S
ABSENCE WAS NOT SERIOUS PROBLEM; DOES THIS NEW REQUEST MEAN
MHW CANNOT TAKE OPP TO FSIC WITHOUT TERATOGENICITY DATA?
MHW/CHEM REPLIED IT WOULD BE BETTER TO HAVE SAID DATA IF AT
ALL POSSIBLE AS FSIC MAY REQUEST IT.

5. AGATT REPS VISITED MHW JAN 28, TO CONFIRM MHW FIVEW RE
INSPECTION ON WAXES. WERE ASSURED THAT INSPECTION PROCEDURES
WOULD NOT CHANGE AFTER MARCH 1 BUT IF ANY PROHIBITED CHEMICALS
LISTED ON IMPORT APPLICATION, WOULD RESULT IN IMPORT BAN ON
SHIPMENT INVOLVED. ONLY FILM FORMING AGENTS (CHEMICALS) THAT
CAN BE LISTED ON FRESH CITRUS AND STILL GET CUSTOMS CLEARANCE
ARE THOSE LISTED REF A. NATURAL WAXES SUCH AS CARNAUBA WAX,
OR CALCIUM SALT OF PARTIALLY DIMERIZED ROSIN (POLY-PALE TYPE
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WAXES) AND SHELLAC NEED NOT BE LISTED ON IMPORT APPLICATION.
MHW HAS NOT "APPROVED" POLY PALE TYPE WAXES, (SINCE THEY ARE
NATURAL THEY NEED NOT BE APPROVED). MHW HAS SIMPLY DETERMINED
THAT POLY-PALE TYPE WAXES ARE NATURAL.

6. DURING VISIT JAN 28 MHW REAFFIRMED THEIR DESIRE TO RECEIVE
TERATOGENICITY DATA ON OPP, IF CURRENT CLIMATE HOLDS, MHW
SHOULD HAVE NO DIFFICULTY TAKING OPP TO FSIC WITHOUT SUCH

DATA, BUT IT IS CONCEIVABLE THAT OPPOSITION FSIC MEMBERS OR OTHERS WITH INFLUENCE WILL DEMAND SUCH DATA. MHW REGULATIONS LIST SUCH DATA AS NECESSARY FOR APPROVAL OF NEW FOOD ADDITIVE IF IT IS CONSIDERED POSSIBLE THAT CHEMICAL IN QUESTION COULD CAUSE BIRTH DEFECTS.

7. AGATT REPS MET WITH DR Y. SHIRASU, DIR OF TOXICOLOGY, INSTITUTE OF ENVIRONMENTAL TOXICOLOGY (IET) (TRANSLATED AS "AGRIC CHEMICAL RESIDUE RESEARCH INSTITUTE" IN PREVIOUS CABLES ON MATTER). SHIRASU HAS WORKED THREE YEARS (1963-69 IN U.S. AT NATL INSTITUTE OF HEALTH ON U.S. GOVT GRANT. HE GAVE BRIEF ACCOUNT OF HIS RECENT VISIT TO U.S. RE OPP/TBZ ISSUE, REFERRING TO EPA'S NOTICE PUBLISHED IN FEDERAL REGISTER OF JUNE 25, 1975 RE "HAZARDS TO HUMANS AND DOMESTIC ANIMALS."

8. ACCORDING TO SHIRASU, MUTAGENICITY RESEARCH ON OPP/TBZ WILL BE STARTED ASAP. HE NOW "MAKING THE ROUNDS" TO GET FINANCING FIRMED UP (WILL COST 7-10 MILLION YEN PER CHEMICAL) AND ACQUIRE NECESSARY SAMPLES OF CHEMICALS. HE ASSURES US THERE SHOULD BE NO GREAT CONCERN RE WHETHER CHEMICALS WILL PROVE TO BE MUTAGENS. SAYS HE HAS DONE MUTAGENICITY SCREENING TESTS (USING MICRO-ORGANISMS) ON ABOUT 170 AG CHEMICALS, INCLUDING MANY FUNGICIDES, AND ALTHOUGH SUCH TEST IS VERY SENSITIVE, ONLY 9 OR 10 OF 170 CHEMICALS TESTED POSITIVE. HE BELIEVES WHEN SAID CHEMICALS ARE SUBJECTED TO HIGHER LEVEL TESTS (USING RATS) PROBABLY ALL WILL TEST NEGATIVE (NON-MUTAGENETIC).

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AGR-05 STR-04 PA-01 PRS-01 /099 W

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9. SHIRASU HOPES TO GET TESTS STARTED BY MID-FEB, AND WILL RUN VARIOUS TESTS IN PARALLEL FASHION TO SAVE TIME. HE THINKS 3 TO 5 MONTHS WILL BE NECESSARY TO COMPLETE TESTS. THEN PERHAPS ONE OR TWO MONTHS FOR FINAL APPROVAL, INCLUDING FSIC REVIEW AND RECOMMENDATIONS.

10. SHIRASU MOST ANXIOUS TO AVOID ANY PUBLICITY ON MATTER, ESPECIALLY WHILE RESEARCH IN PROGRESS. HEAVY SPOILAGE OF FRUIT AND RESULTING HIGH PRICES IN SUMMER COULD LEAD TO TOO MUCH INTEREST ON PART OF PRESS. IN THIS RESPECT, PROVISIONAL APPROVAL LEAK TO WRONG PERSONS, COULD BE VERY COUNTERPRODUCTIVE.

11. SHIRASU IMPLIED THERE IS SERIOUS QUESTION WHETHER CURRENT FOOD SANITATION LAW WILL PERMIT PROVISIONAL APPROVAL UNDER ANY CIRCUMSTANCES, BUT AS RESEARCH PROGRESSED, THERE MAY COME A POINT WHERE PEOPLE IN CHARGE MAY BECOME IT PROPER TO CALL FSIC TOGETHER TO CONSIDER APPROVAL PENDING FINAL RESEARCH REPORT. BUT LAW MAY NOT PERMIT THIS.

12. RE TERATOGENICITY RESEARCH, SHIRASU WAS AWARE THAT DATA ON OPP IS NOT AVAILABLE. HE SAID HE WOULD DISCUSS MATTER WITH MHW/CHEM AND HE MAY DECIDE TO DO SAID RESEARCH ALONG WITH MUTAGENICITY RESEARCH. HE SAID IT WOULD TAKE 4 TO 6 MONTHS

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TO DO TERATOGENICITY RESEARCH.

13. COMMENTS: AGATT FEELS PROGRESS IS BEING MADE AND THAT U.S. CITRUS INDUSTRY WILL DO WELL TO WAIT PATIENTLY, TAKING EVERY PRECAUTION TO KEEP ISSUE OUT OF PRESS. DR SHIRASU SUGGESTION THAT TERATOGENICITY RESEARCH ON OPP (SAID DATA NOW AVAILABLE ON TBZ) BE DONE PARALLEL TO HIS OPP/TBZ MUTAGENICITY STUDIES MAY BE VERY WISE. CONCEIVABLE THAT WITHOUT SAID DATA EFFORTS TO GET FINAL APPROVAL WITHIN NEXT 5 TO 7 MONTHS COULD BE FOILED AT LAST MOMENT. FINANCING MAY BE PROBLEM. IF DOW CHEMICAL NOT WILLING TO HELP RE TERATOGENICITY PERHAPS U.S. CITRUS INDUSTRY COULD TAKE MATTER UNDER CONSIDERATION. FUNDS FOR MUTAGENICITY STUDIES (47,000 TO 67,000 DOLLARS) WILL APPARENTLY BE BORNE BY JAPANESE IMPORTERS WITH PROBABLY SOME HELP FROM MERCK/TOKYO. HODGSON

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RESEARCH, CITRUS FRUITS, WAXES, FUNGICIDES, FOOD ADDITIVES, FOOD & DRUG REGULATIONS, IMPORT CONTROLS
Control Number: n/a
Copy: SINGLE
Draft Date: 30 JAN 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: RELEASED
Disposition Approved on Date:
Disposition Authority: morefirh
Disposition Case Number: n/a
Disposition Comment: 25 YEAR REVIEW
Disposition Date: 28 MAY 2004
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976TOKYO01445
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760037-0024
From: TOKYO
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t1976013/aaaaabrc.tel
Line Count: 218
Locator: TEXT ON-LINE, ON MICROFILM
Office: ACTION EA
Original Classification: LIMITED OFFICIAL USE
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: LIMITED OFFICIAL USE
Previous Handling Restrictions: n/a
Reference: 76 TOKYO 761, 76 TOKYO 840
Review Action: RELEASED, APPROVED
Review Authority: morefirh
Review Comment: n/a
Review Content Flags:
Review Date: 02 JUN 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <02 JUN 2004 by GarlanWA>; APPROVED <02 JUN 2004 by morefirh>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: CITRUS WAXES AND FUNGICIDES DEPARTMENT PASS AGRICULTURE FOR FITZSIMMONS
TAGS: ETRD, EAGR, JA
To: STATE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006